

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Application No. (TO BE ASSIGNED)

Filed (TO BE ASSIGNED)

Original Patent No. 6,245,758

Issued: June 12, 2001

Patentees: Michael K. Stern and Daniela Salvemini

Title METHODS OF USE FOR PEROXYNITRITE DECOMPOSITION CATALYSTS,  
PHARMACEUTICAL COMPOSITIONS THEREFORCOMMISSIONER OF PATENTS AND TRADEMARKS  
WASHINGTON, D.C. 20231

August 15, 2001

PRELIMINARY AMENDMENT A UNDER 37 C.F.R. §1.173 AND  
REQUEST UNDER 37 C.F.R. §1.607 FOR DECLARATION OF INTERFERENCE

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

Prior to the first Office action in the above-referenced application, please enter the following amendments:

Please enter the following new claims:

23. A method of effecting oxidoreduction in a patient comprising administering to said patient a metallic porphyrin complex having substituents on the methine carbons of the porphyrin, in an effective, nontoxic amount, so that said complex is reduced by a reductant present in said patient and reoxidized by O<sub>2</sub><sup>-</sup> present in said patient.

24. The method according to claim 23 wherein said substituents on said methine carbons are such that said metallic porphyrin complex, in vivo, has superoxide dismutase activity.

25. The method according to claim 24 wherein said substituents comprise a pyridyl or phenyl group.
26. The method of claim 23 wherein said metal or manganese, iron, copper, cobalt or nickle.
27. The method of claim 26 wherein said metal is manganese.
28. The method according to claim 23 wherein said substituents on said methine carbons are the same.
29. The method according to claim 28 wherein each of said methine carbons bears a substituent.
30. The method according to claim 28 wherein said metal is manganese, iron, copper, cobalt or nickle.
31. The method according to claim 30 wherein said metal is manganese.
32. The method according to claim 29 wherein said metal is manganese, iron, copper, cobalt or nickle.
33. The method according to claim 32 wherein said metal is manganese.

REMARKS AND COMPLIANCE WITH 37 C.F.R. §1.607

The claims submitted herewith are presented for purposes of interference with US patent 6,103,714.

Proposed Count

Applicants propose the following count for interference:

“A method of effecting oxidoreduction in a patient comprising administering to said patient a metallic porphyrin complex having substituents on the methine carbons of the porphyrin, in an effective, nontoxic amount, so that said complex is reduced by a reductant present in said patient and reoxidized by  $O_2^-$  present in said patient.”

Correspondence of Claim 1 of US 6,103,714 to the Count

Claim 1 is identical to the proposed count.

Correspondence of Claims of the Instant Application to the Proposed Count

Each of newly submitted claims 23-33 correspond to the proposed count, and claim the same invention as claims 1-3, 6-7, 10-13, and 16-17 of the '714 patent.

New claim 23 is identical to the proposed count. The additional claims are identical to the dependent claims of the '714 patent.

Support in the Instant Patent Application for Claims Submitted by This Amendment

Claim 1 of the '714 patent claims a method of effecting oxidoreduction in a patient by administering to the patient a metallic porphyrin complex having substituents on the methine carbons of the porphyrin, in an effective, non-toxic amount, so that said complex is reduced by a reductant present in the patient and reoxidized by  $O_2^-$  which is present in the patient. The specification of the '714 patent discloses a metallic porphyrin complex with specified substituents on the methine carbons. Specifically, the '714 specification discloses a metallic porphyrin almost identical to the one disclosed in Structure I of the above-designated application in that the ring

structure is the same and the substituents overlap as well. For example, the '714 patent discloses manganese as the metal in the porphyrin and the following substituents on the methine carbons of the porphyrin ring: 4-pyridyl, 1-methyl-4-pyridyl, and (trimethylammonio)phenyl. *See* Figure 1 of the '714 patent. The instant application discloses the same ring structure as the '714 patent wherein manganese can be the metal and pyridyl, phenyl, and/or N alkylpyridine are possible substituents. Therefore, the '714 patent and the instant application have overlapping species of metallic porphyrin structures covered by their respective claims.

Further, both the '714 patent and the instant application claim that the described metallic porphyrin structure has superoxide dismutase activity. *See e.g.* col. 1, lines 14-21 and example 13 of the instant application. *See also*, claim 2 of the '714 patent.

For these reasons, Applicants request the Examiner to declare an interference between this Application and U.S. Patent No. 6,103,714.

#### Support in Application 08/242,498 for Claims as Submitted by This Amendment

The above-designated patent application is a continuation of U.S. Serial No. 08/431,593, filed May 1, 1995, which is a continuation-in-part of US Ser. No. 08/242,498, filed May 13, 1994. Upon information and belief there is support in the original disclosure, US Ser. No. 08/242,498, to declare this interference.

#### Requirements of 35 U.S.C. §1.135(b) are Met

The '714 patent issued August 15, 2000. Since the instant amendment is being submitted August 15, 2001, one year from the grant date of '714, this constitutes a timely submission of claims for interference under 35 U.S.C. §1.135(b).

#### Statement Under 37 C.F.R. §1.608

Because the effective date of this application is before the effective date of the '714 patent, applicants submit that they have a basis for judgment relative to the patentee of the '714 patent in an interference.

Basis for Declaration of Interference

As set forth in 37 C.F.R. §1.601(j), an interference in fact exists if:

“at least one claim of a party that is designated to correspond to a count and at least one claim of an opponent that is designated to correspond to the count define the same patentable invention.”

As discussed above, claims 1-3, 6-7, 10-13, and 16-17 of the '714 patent, and the disclosure of this application and its claims 1-22 as presented herewith, are all directed to the same invention that is defined in the proposed count. Accordingly, it is respectfully submitted that the basis for declaration of interference is established under 35 U.S.C. §135 and 37 C.F.R. §1.601, 1.606, 1.607, 1.608, and 1.611.

Conclusion

In view of the foregoing, it is respectfully submitted that new claims 23- 33 are patentable to Applicants, and should be allowed for purposes of interference.

It is further respectfully submitted that an interference between the instant application and US patent 6,245,758 should be declared.

A check in the amount of \$988.00 is enclosed in payment of the reissue application fee.

The Commissioner is hereby authorized to charge any deficiency or overpayment of the required fee to Deposit Account No. 19-1345.

Respectfully submitted,



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